JUL 2 6 2002

K011329

Attachment

510(k) Summary
Premarket Notification [510(k)]
E. Benson Hood Laboratories, Inc. Acoustic Pharyngometer
Date Prepared: October 24, 2001

1. Submitter:

E. Benson Hood Laboratories, Inc.
575 Washington Street
Pembroke, MA 02359

Contact:

Lewis Marten, President
(781) 826-7573
1-800-942-5227
Fax (781) 826-3899

2. Proprietary Name: Eccovision Acoustic Diagnostic Imaging Acoustic Pharyngometer
Common Name: Pharyngometer
Classification Name: Rhinoanemometer

3. Statement of Equivalence/Identification of Predicates

The device is substantially equivalent to the Hood Acoustic Rhinometer cleared under K921452, also known as the Eccovision Acoustic Rhinometer, manufactured by E. Benson Hood Laboratories, Inc.

4. Device Description

The device uses acoustic signaling processing technology to provide a graphical representation of airway patency as a function of distance from the airway opening. A measurement is obtained by passing a signal along a probe positioned in the mouth and recovering the signal by use of two microphones. The signal is processed by the computer and displayed on a screen or relayed to a printer, detailing the cross-sectional area of the airway as a function of distance from the teeth. Specifically, the system, an acoustic reflectometer, uses amplitudes and arrival times of acoustic returns to construct the area-distance function – a plot of cross-sectional area of the airway as a function of distance from the airway opening.

The device is composed of a mouthpiece, wave tube, speaker, microphone, filter strips, acoustic device, C.P.U., printer, monitor, P.C. board, software and source code.

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The device is composed of a mouthpiece, wave tube, speaker, microphone, filter strips, acoustic device, C.P.U., printer, monitor, P.C. board, software and source code.

5. Intended Use

The device is intended to measure the upper respiratory airway by means of acoustic reflection. The predicate is intended to measure the nasal cavity by means of acoustic reflection. Both are merely measurement devices and do not make diagnostic claims. The devices use the same technology and scientific principles to make these measurements.

6. Technological Characteristics

The system consists of a mouthpiece, wave tube, speaker, microphone, filter strips, acoustic device, C.P.U., printer, monitor, P.C. board, software and source code. The acoustic device, monitor, printer and C.P.U. are identical to those in the predicate. The other components are insignificantly different. The P.C. board has two insignificant differences – the rhinometry card contains the first and second stage of the differential instrumentation amplifier, whereas in the pharyngometry card the first stage of the amplifier is moved to the wave tube, which eliminates cross talk in the wave tube and maintains device performance. Both devices use a band pass filter, but there is a slight difference in the low frequency section, which is insignificant because out of band noise is sufficiently removed in both cases. The minor differences in software and source code have been validated and assure that the device performs in the same manner as the predicate. The differences in the wave tubes of the subject and predicate device are that they differ in size, and in the subject device a mouthpiece is used instead of a nose tip, two microphones are used to separate the incident from the reflected pulses and a filter is used since the patient breathes during the assessment. Finally, the speakers differ in size in order to accommodate the difference in the physical size of the wave tubes and the pharyngometry speaker has a higher response (in the frequency range 150Hz to 800Hz) to increase signal strength in this frequency range and result in less variability in measurements in the presence of breathing.

Acoustic Rhinometer -vs- Acoustic Pharyngometer

Items	Acoustic Rhinometer	Acoustic Pharyngometer	Comments
1. C.P.U.	Yes	Yes	Identical
2. Printer	Yes	Yes	Identical
3. Monitor	Yes	Yes	Identical
4. P.C. Board	Yes	Yes	Insignificantly different, see note 1*
5. Software	Yes	Yes	Insignificantly different, see note 2*
6. Source Code	Yes	Yes	Insignificantly different, see note 2*
7. Acoustic Device	Yes	Yes	Technology is identical
8. Nosetip/Mouthpiece	Yes	Yes	Identical functions-matches structure to be measured
9. Wave Tube	Yes	Yes	Insignificantly different, see note 3*
10. Speaker	Yes	Yes	Insignificantly different, see note 4*
11. Microphone	Yes	Yes	Insignificantly different, see note 5*

Eccovision Family Matrix Notes:

Note 1 P.C. Board:

There are two channels on the Pharyngometer and one on the Rhinometer. These channels all perform the same functions. There are two insignificant differences between the channels on the Pharyngometer and the channel on the Rhinometer.

1. The Rhinometer and Pharyngometer contain identical differential instrumentation amplifiers. The rhinometry card contains the first and second stage of the differential instrumentation amplifier. In the pharyngometry card, the first stage of this amplifier is moved to the wave tube. This eliminates cross talk in the wave tube cable, thereby maintaining a level of accuracy equivalent to that of the Rhinometer. The performance of the device is unaffected because the circuits are electrically identical and the components are the same.

2. Both the Pharyngometer and Rhinometer cards use a band pass filter. The pass band on both is from 100 Hz to 10 kHz. The high frequency section (10 kHz) is identical on all filters. There is a slight difference in the low frequency section (100 Hz). The attenuation from 0 – 100 Hz in the Pharyngometer filter is less than the Rhinometer filter. This difference is insignificant because out of band noise is sufficiently removed in both cases. During the development of the Pharyngometer, specifically during lab and design testing, it was determined that a filter with less attenuation than the filter used in the Rhinometer was satisfactory. The filters used on the Pharyngometer could be used on the Rhinometer and would not affect the results.

Note 2 Software and Source Code:

The user controls both devices in the same manner. The differences between the devices in the PRINT and SAVE modes are due to slight differences in formatting which have no effect on device performance because the devices are based on the identical platform technology which uses sound to measure cross-sectional area. In the ACQUIRE mode in the Pharyngometer, a two-channel driver, as opposed to a one-channel driver, is used to acquire patient data, and has no affect on product performance. These differences have been validated to assure that the device performs in the manner intended.

Note 3 Wave Tube:

The differences between the two wave tubes are as follows:

1. With the Pharyngometer a mouthpiece instead of a nose tip is used to interface with the patient.
2. Two microphones are used to separate the incident pulse from the reflected pulse with the Pharyngometer. The exiting (incident) pulse passes by microphone (a) and then by microphone (b). The entering (reflected) pulse passes by microphone (b) and then by microphone (a). The sequence of pickup [(a) – (b); (b) – (a)] defines the direction of pulse which allows for the measurement of a longer distance with a short tube. The concept that one can separate incident and reflected pulses in a short tube with two microphones versus a long tube with one microphone was validated.
3. The oral airway changes during certain breathing maneuvers so the Pharyngometer must allow the patient to breathe in order to capture these changes. The end of the Pharyngometer wave tube is open to permit breathing. A standard 3M filter is used to isolate the microphones and speaker from the patient's expired air. In contrast, the nasal airway does not change and therefore the Rhinometer does not have to allow the patient to breathe. The end of the Rhinometer wave tube is closed and a filter is unnecessary.
4. The tube for the Pharyngometer can be detached and cleaned. The cleaning is not necessary for the performance of the device and is only done for hygienic purposes.
5. The internal diameter of the wave tube is approximately 0.75 inches, which more closely matches the internal diameter of the oral airway than does the 0.50-inch diameter of the predicate's wave tube for the nasal cavity. The advantage of having wave tube diameter more closely match the diameter of the airway being measured is to maximize the amount of acoustic energy that is delivered to the airway which increases the signal to noise ratio, thus minimizing the demand on the hardware and software.

   The lengths of both wave tubes are comparable; the Pharyngometer wave tube is slightly shorter than the Rhinometer wave tube. The determining factor in the length of the wave tube is one of ergonomics with the users.

The technology is identical in both applications. The differences do not affect performance of the device because one and two microphone systems have been proven to be equivalent.

Note 4 Speaker:

There are no differences in functional requirements or speaker construction technology between the two devices. Both speakers are from standard stock and are a typical fixed magnet and coil type with a nominal 8 ohms impedance. The Pharyngometer speaker is slightly smaller than the Rhinometer speaker. The physical size of the speakers is different to accommodate the difference in the physical size of the wave tubes. The Pharyngometer speaker has a higher response in the frequency range of 150 Hz to 800 Hz. This increases signal strength in this frequency range and results in less variability in measurements in the presence of breathing. It also allows measurements to be made in airways at increased distances.

Note 5 Microphone:

The microphones in both devices are identical; the Pharyngometer wave tube utilizes two microphones versus one, which is used in the Rhinometer. With a two-microphone system the length of the airway measured can be longer without increasing the length of the wave tube. This can be done because the two microphones separate the incident and reflected pulses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 6 2002

E. Benson Hood Lab, Inc.
c/o Lewis Marten
575 Washington St.
Pembroke, MA 02359

Re: K011329
Trade/Device Name: Eccovision Acoustic Diagnostic Imaging Acoustic Pharyngometer
Regulation Number: 21 CFR 868.1800
Regulation Name: Rhinoanemometer
Regulatory Class: Class II
Product Code: BXQ
Dated: May 2, 2002
Received: May 3, 2002

Dear Mr. Marten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address. http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

Premarket Notification [510(k)]: K011329

E. Benson Hood Laboratories, Inc. Acoustic Pharyngometer

Indications for Use:

The Acoustic Pharyngometer is intended to measure the upper respiratory airway by means of acoustic reflection.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____

(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K011329